



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/752,899 | 12/29/2000 | Frank J. Bunick | MCP-0262 | 9623 |

7590 05/19/2006

Philip S. Johnson, Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

| EXAMINER |
|----------|
|----------|

CHANNAVAJJALA, LAKSHMI SARADA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/752,899

Applicant(s)

BUNICK ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of response dated 2-23-06 is acknowledged.

Claims 1-5 and 7-13 are pending. Claim 6 was inadvertently included in the list of pending claims. However, claim 6 has been canceled.

Claim Rejections - 35 USC § 103

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,327,076 to Puglia et al (Puglia) in view of US 5,380,541 to Beyts et al (Beyts).

Puglia teaches compressed soft chewable antacid tablets that are break resistant and yet fast disintegrating upon chewing. The tablet of Puglia containing antacid particles is mixed with oil or fat absorbed on a fat-absorbing material such as microcrystalline cellulose and tablet binders such as dextrose hydrate, sugars etc (col. 2, lines 46-67, Example 1 & col. 5, lines 22-32). Puglia further teaches addition of sweetening agents such as sugar, saccharin, aspartame etc in the antacid composition (col. 6, lines 40-54). In addition to antacid, Puglia teaches chewable tablets comprising other medicaments such as aspirin, vitamins etc (col. 9). Puglia teaches addition of fats or oil in an amount of 2% to 45%, which includes the claimed percentage of fat (col. 4, lines 53-65). Puglia does not specifically teach particulate dextrose monohydrate. However, the reference teaches blending the dextrose monohydrate with other components of the tablet (col. 8) and thus obviously resulting in a particulate material before being compressed. Puglia fails to teach sucralose of the instant claims.

Art Unit: 1615

Beyts teaches sucralose containing ingestible compositions such as medicaments, beverages, etc. Beyts teaches that a synergy in obtaining sweetness is observed with sucralose and other saccharides such as glucose, fructose, mannitol, sorbitol, or fructose mixed with glucose. Example 1 of Beyts shows the synergy of sucralose with various sweeteners such as fructose etc., and the list of sweetener blends with sucralose in col. 5, specifically mentions a combination of dextrose monohydrate and sucralose that reads on the instant claimed components. Further example 9 is directed to a peppermint tablet, which meets the description of a chewable tablet. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add a synergistic combination of sucralose with other sweeteners such as fructose, dextrose monohydrate, sucrose, glucose etc., of Puglia because Beyts suggests that sucralose is effective in reducing the calorie level in the final preparation of foodstuff, medicaments, beverages etc, and is much sweeter than the sucrose or other sweeteners. Accordingly, one of an ordinary skill in the art would have expected to sweeten the chewable tablet composition of Puglia by adding sucralose together with other sweeteners such that the sweetness intensity of the composition is increased due to the presence of sucralose and yet with low calories.

Response to Arguments

Applicants' arguments filed 2-23-06 have been considered but not found persuasive.

Applicants argue that instant claims require a matrix that is substantially free of non-saccharide, water-soluble polymeric binders and that the rejection fails to identify

Art Unit: 1615

where in Puglia such a limitation can be found. It is argued that the rejection is neither not supported by “cold hard” facts nor there is a requisite teaching, suggestion or motivation for the required claim limitation. In this regard, applicants direct examiner’s attention to the specific non-saccharide materials on page 5 of the specification that are excluded by the claim limitation. Applicants’ arguments are not found persuasive because instant specification states that dry binders such as microcrystalline cellulose can be minimized or eliminated by the use of dextrose monohydrate or can be used at low levels i.e., preferably less than 20%, more preferably less than 10% or substantially free. However, instant specification does not define as to what % of any of the binders is allowed by the term “substantially free of”. Puglia also teaches from about 10% to 30% or preferably 10% to 20% microcrystalline cellulose (non-saccharide, water-soluble binder) as a fat-sorbing material (col.5 lines 5-20 of Puglia, referred by applicants on page 5 of their response), which is present within the instant claimed limits.

Applicants argue that Puglia requires a slip agent from 0.75 to 1.5% by weight of the tablet (or 0.5% to 1.5% of the total tablet), which includes a carboxymethyl cellulose gum and is a non-saccharide, water-soluble binder. Applicants argue that Example 1 of Puglia affirmatively employs 0.75% of the above gum as a binder and argue that the reference does not teach or suggest the claimed tablet that is less than 5% by weight of fat and is substantially free of non-saccharide, water-soluble binder. Applicants’ arguments are not persuasive because the limitation “substantially free of non-saccharide, water-soluble binder” has not been defined and thus does not set a specific

Art Unit: 1615

lower limit to the amount of the binder. In the absence of such, the teaching of 12.27% microcrystalline cellulose together with 0.75% carboxymethyl cellulose gum, in example I of Puglia accounts only for a total of 13% binder by total weight of the tablet, which is still within the preferable limits according to the instant specification.

With respect to the combination of the references, applicants argue that Beyts nowhere discloses or suggests the desirability of including sucralose in a chewable tablet and that the example 9 of Beyts at best represents a succulent tablet. It is argued that examiner cannot establish obviousness by locating references, which desire various aspects of patent applicants' invention without also providing evidence of the motivating force, which would impel one skilled in the art to do what the patent applicant has done.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Puglia and Beyts teach tablet preparation. Puglia teaches addition of tableting sugars and sweetening agents such as sucrose, sugar alcohols, xylitol, sorbitol, saccharin etc. (example 1 and col. 6, lines 40-44). Beyts suggests synergistic effect with a combination of sucralose and other sweetening agents such as glucose, fructose, sorbitol etc. Thus,

Art Unit: 1615

the motivation to combine the sucralose with the sweeteners of Puglia comes from the desirability of sweeteners in the chewable tablet of Puglia and the teaching of synergy between sucralose and the conventional sweeteners (Beyts).

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

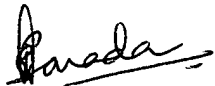
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

Art Unit: 1615

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
May 11, 2006